

Notice of Allowability

Application No.

10/679,258

Examiner

Lori A. Clow, Ph.D.

Applicant(s)

ORLANDI ET AL.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the interview of 4/23/07 and reply of 1/25/07.
2. ☒ The allowed claim(s) is/are 1-38.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>4/27/07</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>5/19/2005</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel Burke on 25 April 2007.

The application has been amended as follows:

In claim 1, line 5, replace "during a first trimester of pregnancy" with
--during the first trimester of pregnancy --.

In claim 5, line 1, replace "wherein the fetal abnormality developmental central nervous system abnormality is open spinal bifida. " with

--wherein the fetal abnormality is open spina bifida. --

In claim 6, line 9, replace "during a first trimester of pregnancy" with
--during the first trimester of pregnancy --.

In claim 14, line 8, replace "BPD/FD ratios" with
--BPD/OFD ratios --.

In claim 28, line 5, replace "determining a BPD/OFD ratio of the patient's fetus and at least one secondary marker" with

-- determining a BPD/OFD ratio of the patient's fetus during the first trimester of pregnancy and at least one secondary marker--.

In claim 29, line 7, replace “frequency distributions of fetal OFD/BPD ratios and at least one secondary marker” with

-- frequency distributions of fetal OFD/BPD ratios during the first trimester of pregnancy and at least one secondary marker --.

In claim 30, line 13, replace “abnormality” with

-- abnormality and outputting risk results to a user. --

In claim 38, line 1, replace “wherein the developmental central nervous system abnormality is open spinal bifida.” with

--wherein the fetal abnormality is open spina bifida.—

Reasons for Allowance

The following is an examiner’s statement of reasons for allowance:

The prior art does not teach or fairly suggest a method or machine readable medium for assessing a patient’s risk of having a fetus with fetal abnormality comprising determining the patient’s a priori risk of having a fetus with fetal abnormality; determining a BPD/OFD ratio during the first trimester of pregnancy; determining a secondary marker during the first trimester of pregnancy and comparing the two to asses risk, as in claims 1, 6, 28, 29, and 30.

The closest prior art of Wald teaches a method of screening for fetal Down’s syndrome using screening markers. Wald does not specifically teach using the ultrasound marker BPD/OFD in the evaluation of patient risk for having a fetus that is abnormal. Stempfle et al. do teach that biometrical and morphological criteria have been used in fetal screening of Down's syndrome.

However, neither teaches that the method can be performed in the first trimester of pregnancy. The Stempfle study is limited to data collected in the second and third trimester of pregnancy and therefore, teaches away from performing the method in the first trimester of pregnancy. Therefore, the instant invention provides unexpected results over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 1-38 are allowed.

Note: The IDS submitted 5/19/03 was considered in full on 8/12/05. The Examiner inadvertently forgot to initial the column to the left of the cited reference. The IDS is thereby being re-submitted for clarity of the record.

Note: The amendment to claim 30 above, reciting "outputting risk results to a user" is fully supported in Figures 2 and 3. Therefore, no new matter has been introduced.

Note: The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure: 5,772,584.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG

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30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

April 27, 2007

Lori A. Clow, Ph.D.

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Lori A. Clow

Patent Examiner